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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,565	07/20/2001	Robert M. Winslow	490042000100	9103
20583	7590	12/18/2003	EXAMINER	
PENNIE AND EDMONDS			KIM, SUN U	
1155 AVENUE OF THE AMERICAS			ART UNIT	
NEW YORK, NY 100362711			PAPER NUMBER	

1723

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/807,565		WINSLOW ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	John Kim		1723	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-12 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-12 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 16-19 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

1. An abstract on a separate sheet filed 9/16/03 is acceptable.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,646,252 (hereinafter referred to as Berbers et al). Berbers et al teach a method for preparing a modified hemoglobin solution comprising the steps of washing red blood cells with saline solution, lysing red blood cells by exposing the red blood cells with distilled water i.e. hypotonic solution to produce stromata and a hemoglobin solution i.e. hemolysate, separating hemoglobin solution from stromata, mixing the hemolysate with a reagent to chemically modify the hemoglobin to a chemically modified hemoglobin solution via cross-linking and polymerization and sterilizing the chemically modified hemoglobin solution through filtration (see col. 3, lines 2-18; col. 4, line 16 – col. 5, line 16; col. 7, line 48 – col. 9, line 42).
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berbers et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,464,814 (hereinafter referred to as Sehgal et al). Berbers et al teach a method for preparing a modified hemoglobin solution in above paragraph 3. Claims 3-4 essentially differ from the method of Berbers et al in

reciting that the wash solution further comprises an agent for killing bacteria or removing and inactivating organisms. Sehgal et al teach a method for preparing the stroma-free hemoglobin solution wherein wash solution optionally contain antibiotics to minimize bacterial contamination (see col. 5, lines 16-42). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include antibiotics in the wash solution to kill, remove, or inactivate bacteria as suggested by Sehgal et al.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berbers et al as applied to claim 14 above, and further in view of U.S. Patent No. 5,814,601 (hereinafter referred to as Winslow et al). Berbers et al teach a method for preparing a modified hemoglobin solution in above paragraph 3. Claim 16 essentially differs from the method of Berbers et al in reciting that the reagent comprises activated polyethylene glycol to chemically modify the hemoglobin. Winslow et al teach that hemoglobin is modified by a chemical reaction such as crosslinking, polymerization or the addition of chemical groups i.e. polyethylene glycol to form a hemoglobin based oxygen carrier (see col. 3, lines 27-38). It would have been obvious to a person of ordinary skill in the art to chemically modify the hemoglobin by addition of polyethylene glycol to hemoglobin solution in substitution of crosslinking or polymerization in the method of Berbers et al to form hemoglobin-based oxygen carrier as suggested by Winslow et al.

7. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 7-12 are allowed.


9. Applicant's arguments with respect to claims 1-5, 7-12 and 16-19 have been considered but are moot in view of the new ground(s) of rejection. Amended claim 1 and new claim 19 do not contain all the limitation of original claim 1 because the step for measuring the ionic strength of the hemolysate is no longer claimed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
December 15, 2003